

REMARKS

Claim Amendments and New Claims:

Pursuant to the entry of this amendment, claims 1-29 are pending in this application. Regarding the specific amendments to the claims:

Elected claim 9 is amended herein for clarification purposes only. As this amendment does not substantially alter the scope of the claim, it should not be construed as a narrowing amendment.

Newly added claims 26-29 define preferred embodiments of the semi-solid composition utilized in the methods of elected claims 9-11.

Support for the amendments presented herein is found in the specification as originally filed, for example at p. 2, lines 15-27; p. 5, lines 20-29; p. 13, lines 25-27; and p. 16, lines 23-33. Thus, Applicant respectfully submits that no new matter has been added.

Provisional Election:

In response to the restriction requirement issued July 10, 2007, Applicant provisionally elects **with traverse** the invention of Group III, directed to methods of treating skin conditions with a semi-solid composition formulated for topical administration comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutically acceptable carrier. Applicant further provisionally elects diaper rash as the species of skin condition to be treated or prevented. Applicant respectfully submits that the elected invention corresponds to claims 9-11 and 26-29.

Restriction Requirement:

In the Office Action of July 10, 2007, the Examiner requested that Applicant elect one of the following inventions:

- Group I, claims 1-7 drawn to topical compositions comprising polyunsaturated fatty acid fraction from *Nigella sativa*;
- Group II, claim 8, drawn to a method of treating an anal fissure with said composition;
- Group III, claims 9-11, drawn to methods of treating a skin condition with said composition;

- Group IV, claim 12, drawn to a method of treating or preventing inflammation with said composition; and
- Group V, claims 13-25, drawn to methods of treating or preventing infection.

As noted above, so as to be fully responsive to the outstanding Restriction Requirement, Applicant provisionally elects with traverse the invention of Group III, directed to methods of treating skin conditions with a semi-solid composition formulated for topical administration comprising a polyunsaturated fatty acid fraction extracted from *Nigella sativa* L. seeds and a pharmaceutically acceptable carrier. However, Applicant respectfully submits that the outstanding restriction requirement is improper, in whole or in part, because under the statute, if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent and distinct inventions. In this case, the search required for the method of Group III necessarily overlaps with, and indeed is central to, the search required for the other claimed methods that utilize the inventive composition (inventions of Groups II, IV, and V). Accordingly, Applicant respectfully submits that it would not be an undue burden for the Examiner to consider claims 8 and 12-25 together in the present application. Thus, Applicant respectfully requests that the Examiner reconsider the outstanding Restriction Requirement and specifically reconsider examining non-elected claims 8 and 12-25 with the elected invention of Group III, claims 9-11 and 26-29.

Election of Species:

In the outstanding Office Action, the Examiner also indicated that the application contained a number of patentably distinct species. With respect to the invention of Group III, the Examiner indicated that Applicant must specify a particular skin condition to be prevented and/or treated (i.e., one from the group consisting of “psoriasis, eczema, dermatitis, dry, scaly, itchy or flaky skin, diaper rash, athlete’s foot, jock itch, scalp irritations, and dermal infections” as set forth in claim 11). As noted above, so as to be fully responsive, Applicant provisionally elects with traverse the skin condition of diaper rash. However, Applicant respectfully submits that such a requirement is improper, in whole or in part. Furthermore, Applicant respectfully submits that the division of the present invention into distinct species

is unduly restrictive and therefore constitutes an undue burden on Applicant. Accordingly, Applicant requests reconsideration in view of the following remarks:

It is well settled that if the members of a Markush group (e.g., the alternative groupings recited in claim 11) are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all claims on the merits, even though they may be directed to independent and distinct inventions. Moreover, restriction among groups within a Markush claim is *per se* improper if it can be shown that the members of the Markush group share (a) a common utility and (b) a substantial structural feature essential to that utility. In this case, Applicants respectfully submits that the Markush members set forth in claim 11 are so few in number and interrelated that no serious burden would be imposed upon the examiner to search the entirety of the claims. However, in the event the Examiner elects to maintain the instant election of species requirement, Applicant holds in abeyance the examination of the non-elected embodiments upon an indication of allowability of the elected species pursuant to M.P.E.P. § 803.02. In particular, it is noted that “should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended [to the non-elected species]. . . The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim.” M.P.E.P. § 803.02.

Furthermore, as noted above, it is well settled that if the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, *in its entirety*, even though it may include claims to distinct or independent inventions. In this case, it is readily apparent that the search for one skin condition (e.g., diaper rash) would necessarily overlap with that required for the other claimed species (e.g., dermatitis). Accordingly, it appears that search and examination of all species, including the indicated subcomponents, would not constitute an undue burden on the Examiner. As there is no indication that searching multiple species would constitute an undue burden on the Examiner, the species requirement is *per se* improper.

In closing, Applicant wishes to remind the Examiner that upon the allowance of a generic claim, Applicant is entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim. In particular, once a generic claim is allowable, all of the claims drawn to species in addition to

the elected species which require all the limitations of the generic claim will ordinarily be allowable over the prior art in view of the allowability of the generic claim, since the additional species will depend thereon or otherwise require all of the limitations thereof. M.P.E.P. § 806.04(d). Accordingly, Applicant holds in abeyance the examination of claims to the non-elected species upon an indication of allowability of one of more generic claims.

CONCLUSION

The outstanding Office Action set a one-month shortened statutory period for response, response being due on or before **August 10, 2007**. Accordingly, Applicants submit that this response is timely and no fee is required. However, in the event that further fees are required to enter the instant response and/or maintain the pendency of this application, the Commissioner is authorized to charge such fees to our Deposit Account No. **50-2101**.

If the Examiner has any questions or concerns regarding this communication, he is invited to contact the undersigned.

Respectfully submitted,

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